

In re Zetia (Ezetimibe) Antitrust Litigation

**END-PAYOR PLAINTIFFS'
MOTION FOR CLASS CERTIFICATION**

DIRECT TESTIMONY OF LAURA R. CRAFT

5/1/2020

Summary of Opinions

1

1. Available data is extraordinarily comprehensive

2. Each proposed Class Member can be identified with precision

3. Class Exclusions can be implemented with this same data

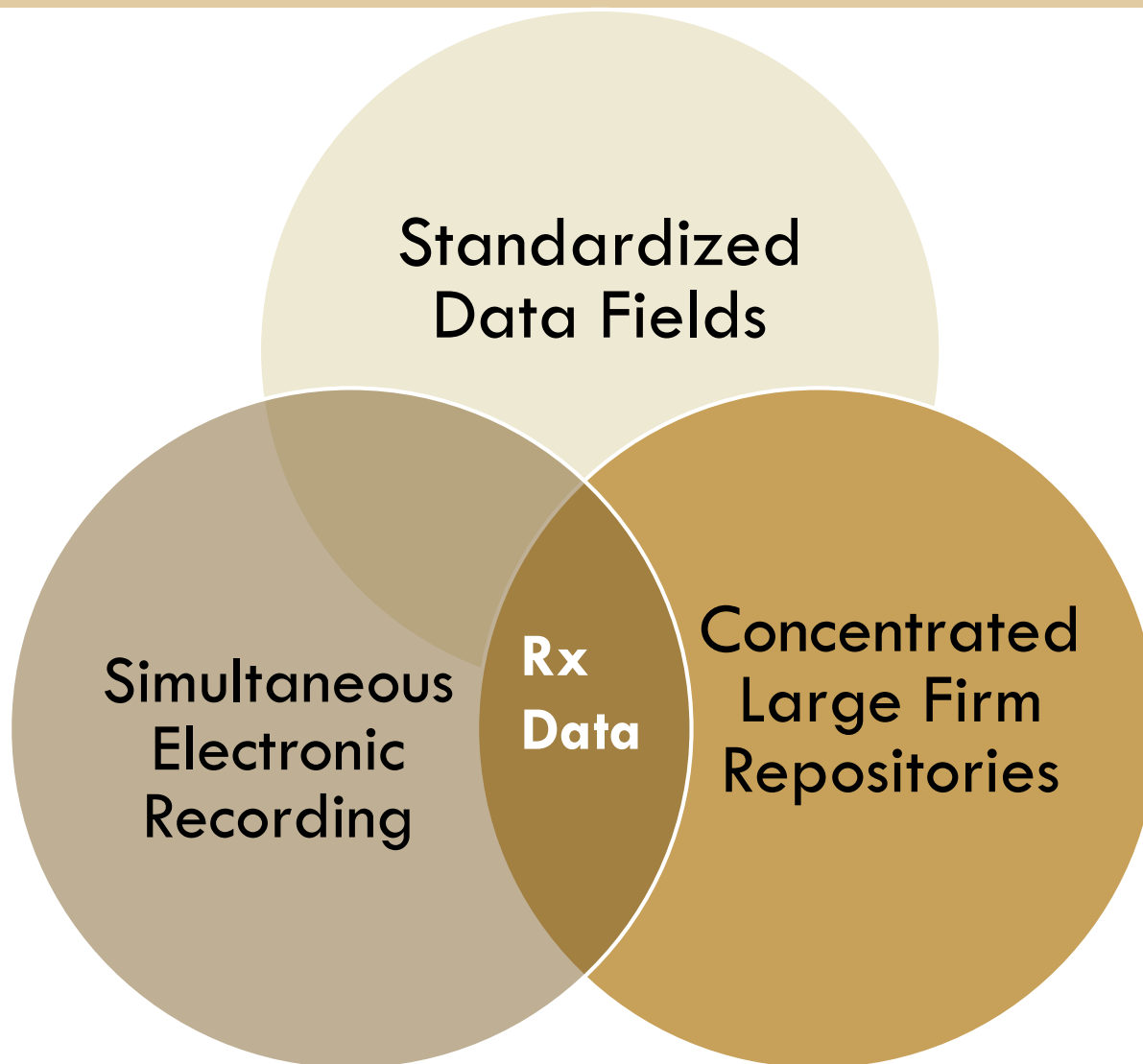
4. Proposed amendments to the Class Definition add no appreciable complexity

2

Availability of Data

Transaction Specific Data for Drug Dispensing

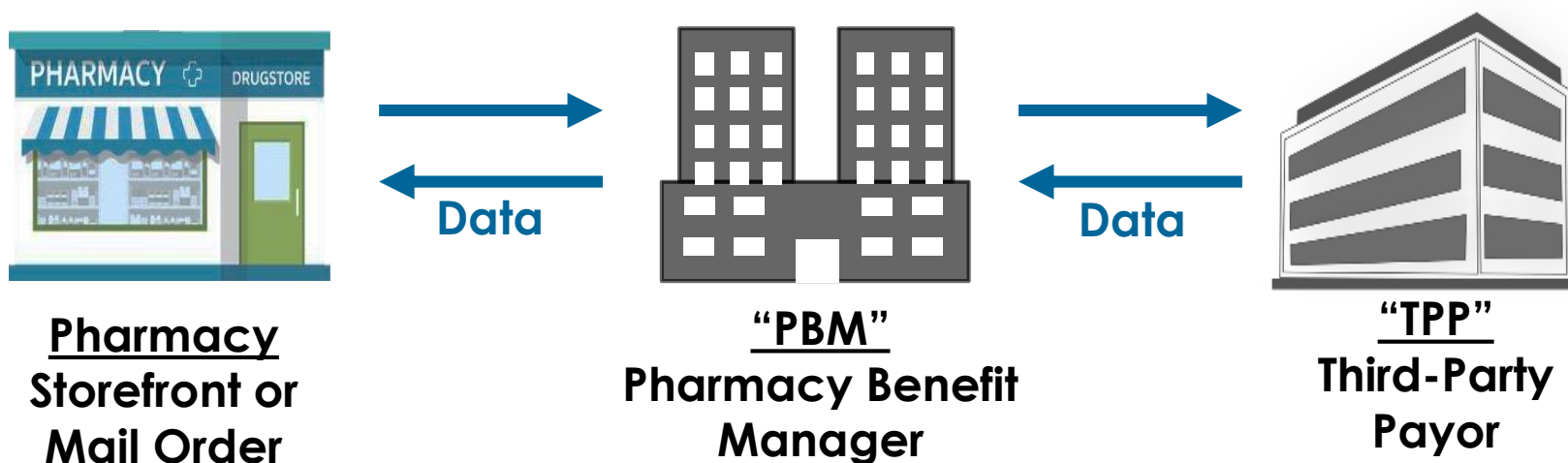
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Instantaneous Data Exchange Powers the System and Creates an Audit Trail

4

Claims Adjudication and Payment With Each Rx Fill



National Drug Code (“NDC”) Uniquely Identifies Each Product Dispensed

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□ **NDC** tells us:

- Manufacturer/packager
- Brand or chemical name
- Brand/generic status
- Dosage strength
- Dosage form (e.g., tablet)
- Package size



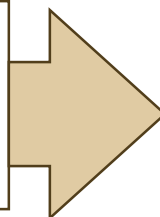
* A few plans use the GPI-14 Code which serves a similar function

Pharmacies and PBMs Are Required to Speak the Same Language



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National Council for Prescription
Drug Programs (NCPDP)
Telecomm. Guidelines



- ▣ Versions 5.1 (1999) and D.0 (2010)
- ▣ Updates have not changed key fields
- ▣ HIPAA mandated since 2003

TPP Identity	
Payer ID	569-J8 & 568-J7 PAYER ID
Plan Group #	301-C1 GROUP ID
Plan ID #	524-FO PLAN ID

Prescription Specifics	
NDC	407-D7 & 436-E1 PRODUCT/SERVICE ID
Quantity	442-E7 QUANTITY DISPENSED
Date of Fill	401-D1 DATE OF SERVICE
Prescription #	402-D2 & 455-EM PRESC./SERVICE REF. NUMBER

Pharmacy Identity	
Unique Pharmacy ID	201-B1 & 202-B2 SERVICE PROVIDER ID

Price and Its Allocation	
Total Price	430-DU GROSS AMOUNT DUE
Make-Up of Price	506-F6 INGREDIENT COST PAID 507-F7 DISPENSING FEE PAID
TPP's Payment	509-F9 TOTAL AMOUNT PAID
Patient Payment	505-F5 PATIENT PAY AMOUNT
Co-pay or Co-insurance	518-FI AMOUNT OF COPAY 572-4U AMOUNT COINSUR.
Applied to Deductible	517-FH AMOUNT APPLIED TO PERIODIC DEDUCTIBLE

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Identifying Class Members

PBM Declarations Confirm TPPs are Identifiable

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Steven Schaper, Caremark (*In Re: Zetia*), March 18, 2020

“Caremark maintains records by which Clients and a Client’s members can be identified for purchases of Zetia or its generic equivalents that Caremark adjudicates on behalf of its Clients.” (¶6)

James Calandriello, Express Scripts (*In Re: Restasis*), April 9, 2019

“Express Scripts maintains records by which Clients and a Client’s members can be identified for purchases of Restasis that Express Scripts adjudicates on behalf of its clients.” (¶7)

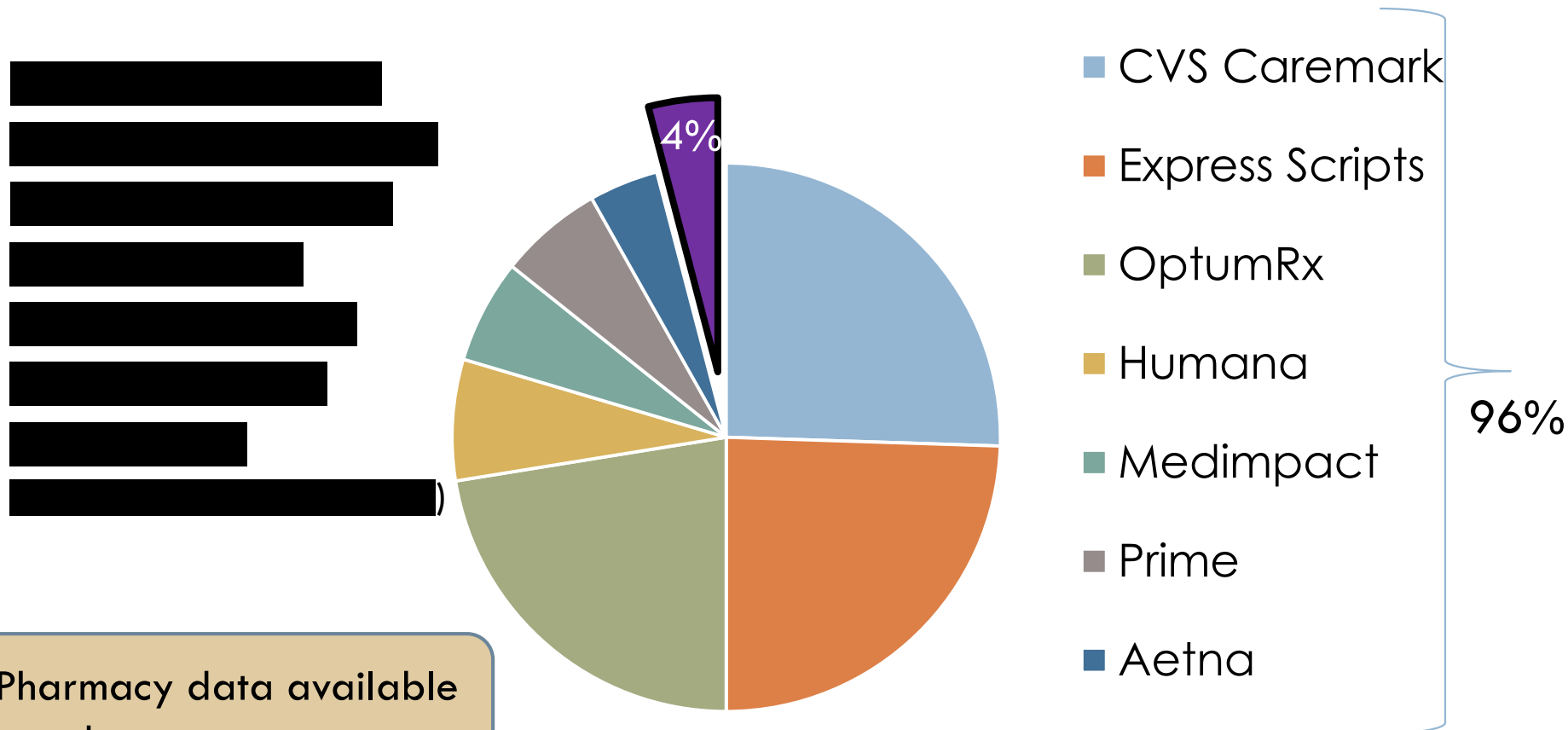
Kent Rogers, OptumRx (*In Re: Restasis*), April 4, 2019

“OptumRx maintains records, in an industry standard format created by the National Council for Prescription Drug Program (NCPDP), by which third-party payors and consumers can be identified on every purchase of Restasis that OptumRx adjudicates on behalf of its third-party payors.” (¶8)

Seven of the Largest PBMs Processed 96% of U.S. Prescriptions in 2017

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PBM Share of Total U.S. Equivalent Prescriptions, 2017



Pharmacy data available
but unnecessary

Drug Channels Institute, The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers (2018)

There is No Reason To Believe Data Has Been Destroyed

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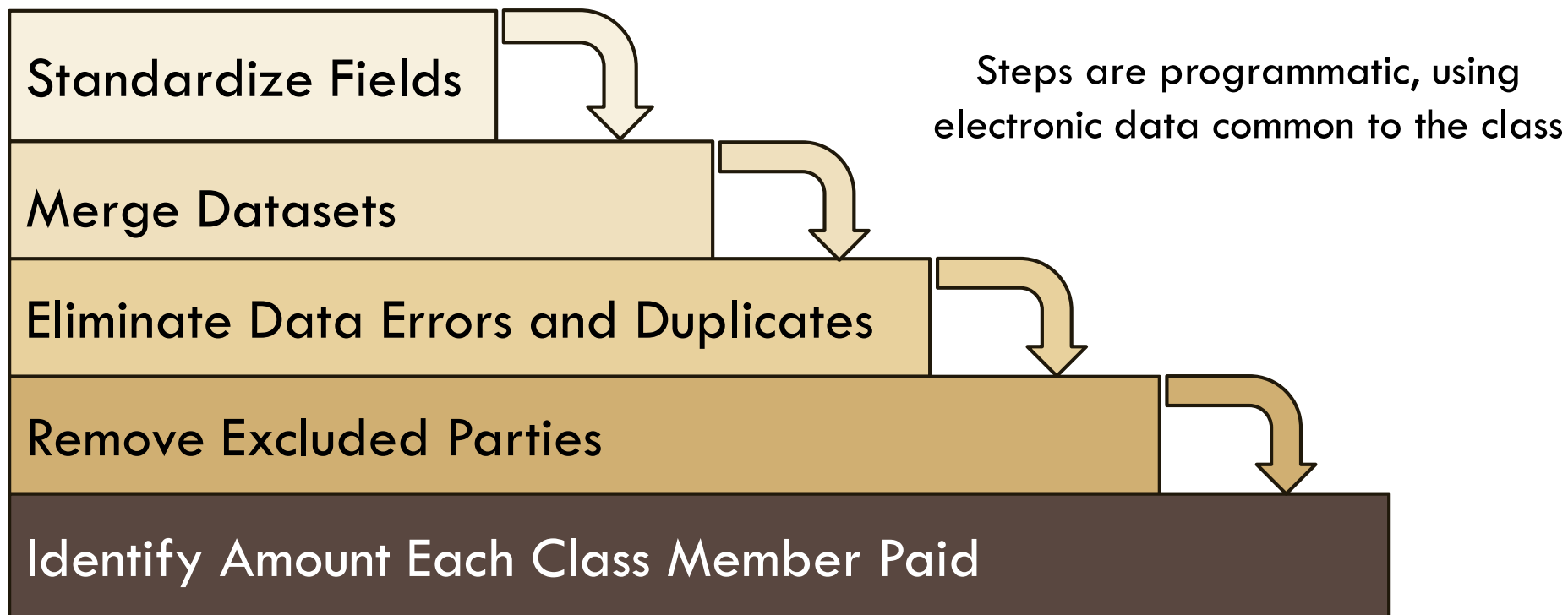
PBMs keep data because:

- ❑ Contractual requirements
(70% of contracts > amended class period)
- ❑ Legal protection
- ❑ Market intelligence
- ❑ Drug use studies
- ❑ Data analysis products
- ❑ Storage is cheap
- ❑ Archiving easy to restore

Mr. Dietz
acknowledges
incentives

Retrieved Data is Relatively Standard and Can Be Formatted for Class-Wide Analysis

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“[T]he data from various sources would be merged, and the EPPs would identify and eliminate data errors, standardize the data, eliminate duplicates, and compile the list”

In re Loestrin 24 FE Antitrust Litig., 410 F. Supp. 3d 352, 400 (D.R.I. 2019)

Methodology is Standard

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“Upon receipt, OnPoint would be able to merge the data from the various PBMs and/or TPPs, identify and eliminate data errors, transform the data to standardize fields, eliminate duplicates, and compile a list reflecting the identities of the Class Members and the dollar amounts and specifics of their Zetia/ezetimibe purchases. Despite raising concerns about whether data transformation and merger are feasible, Mr. Dietz acknowledges that he does not know how these processes are performed and that he lacks expertise in information technology. Converting data from one format to another, if necessary, can be accomplished programmatically. Various software products are capable of converting datasets stored in different programming formats.”

(Craft Rebuttal, at ¶16)

Data From 7 Named Plaintiffs' Is Easily Interpreted

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State
Pharmacy State
Pharmacy State
Abbreviation Code
Phcy_State
State

NDC
Drug ID (NDC)
Drug NDC
NDC
NDC Number (11 Digit)

Dispensing Fee
Dispensing Fee
DispensingFeeBilled
Total Dispensing Fee

Date Filled
Claim Fill Date
Date Filled
Date of Service
DateOfService
Fill Date
Filled Date

Total Drug Cost
Drug Cost
Gross Cost
Total Drug Cost
Total Gross Cost
Patient Pay Amount + TPP Pay

TPP Pay
Amount Paid
Net Plan Cost
Total Amount Paid
Total Net Cost
Total Plan Paid
TotalAmountBilled

Patient Pay
Copay
Member Rx Cost
PatientPayAmount
Total Copay Amount
Total Member Paid
Total Patient Cost
Total Member Amount Paid

Mr. Dietz acknowledges PBMs maintain data dictionaries
(Dietz Dep., 121:24-122:9 & 282:22-283:2)

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Class Exclusions

Class Exclusions Are Straightforward

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Defendants'
Affiliates

Purchasers for
Resale

Direct Purchasers

PBM's

Federal/State
Gov't Entities

Fully-Insured
Health Plans

Defendants Address 3 of the 6 Exclusions

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Defendants'
Affiliates

Purchasers for
Resale

Direct Purchasers

1. PBMs

2. Federal/State
Gov't Entities

3. Fully-Insured
Health Plans

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Exclusions

1. PBMs

There Is No Ascertainability Issue Regarding PBMs

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- Few PBMs
- Most outsource to a larger PBM
- Data identifies TPP who pays (not PBM)
- PBMs are explicitly not Class Members
- No need to identify them

Defendants' argument is that PBMs might absorb some of the TPP loss through:

- ① “Negative Spread Pricing”
- ② Rebate Guarantees

**Unfounded
Damage
Argument**

PBMs Declare Under Penalty of Perjury They Are Not End-Payors

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Steven Schaper, Caremark (*In Re: Zetia*), March 18, 2020

“Caremark’s PBM business is not the ultimate payor of prescription benefits provided by its Clients.” (¶5)

Jon Stocker, Prime Therapeutics (*In Re: Restasis*), March 13, 2019

“As a pharmacy benefits manager, Prime is not a consumer, endpayor, insurer, or reseller of prescription drug products.” (¶7)

Kent Rogers, OptumRx (*In Re: Restasis*), April 4, 2019

“OptumRx is a service provider. As a PBM, it is not a consumer, endpayor, insurer, or reseller of prescription drug products. OptumRx does not consider itself to be paying for its Clients’ prescription drug purchases.” (¶4)

PBMs Bid for TPP Business Using Multiple Fee Structures, But None Pays For Drug Claims

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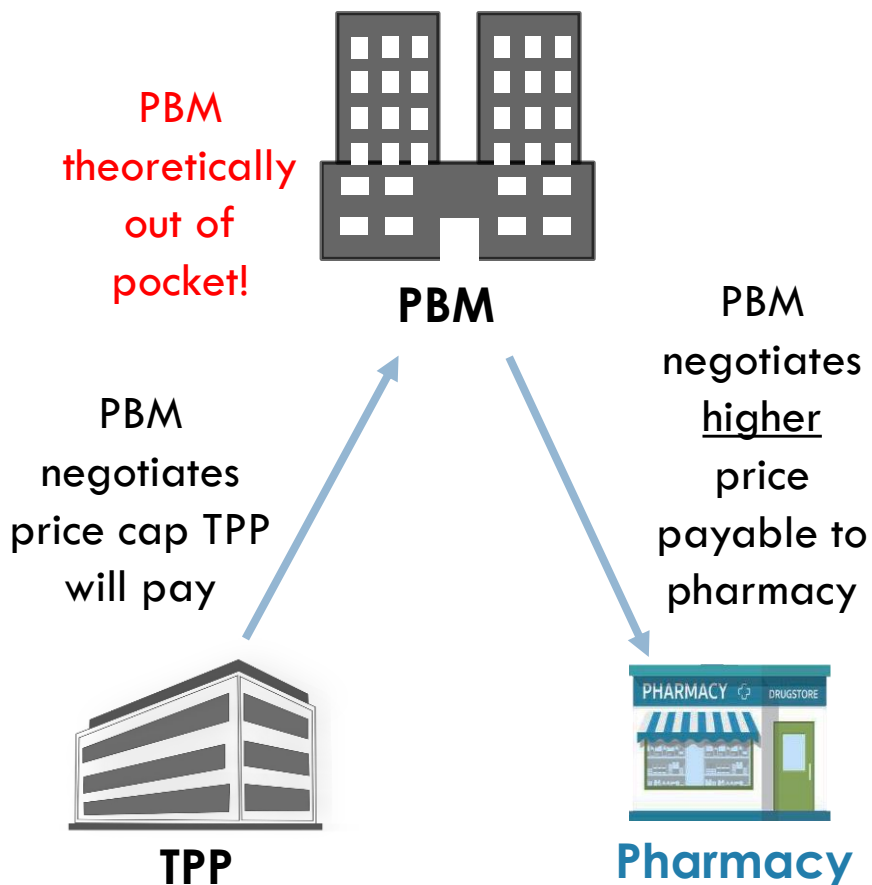
	<u>PBM A</u>	<u>PBM B</u>	<u>PBM C</u>
	“Pass Through”	“Hybrid”	“Traditional”
Equivalent Competitive Pricing (Same \$, Different Form)	Transaction Fees only \$18.60/Rx	50% of Manufacturer Rebates	100% of Manufacturer Rebates
		Further Pharmacy Discounts	
		Transaction Fees \$6.20/Rx	Further Pharmacy Discounts

Mr. Dietz acknowledged these forms of compensation are interchangeable and Transaction Fees are not payments for end purchases.
(Dietz Dep. 228:17-229:14 and 226:16-23)

“Negative Spreads” Are a Theory, Not a Practical Reality

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“Negative” Spread Pricing



Problems with this theory...

1. No evidence it actually happens
2. PBMs highly sophisticated
3. PBMs negotiate both contracts
4. Spread pricing is designed to work the opposite direction (added comp to PBM)

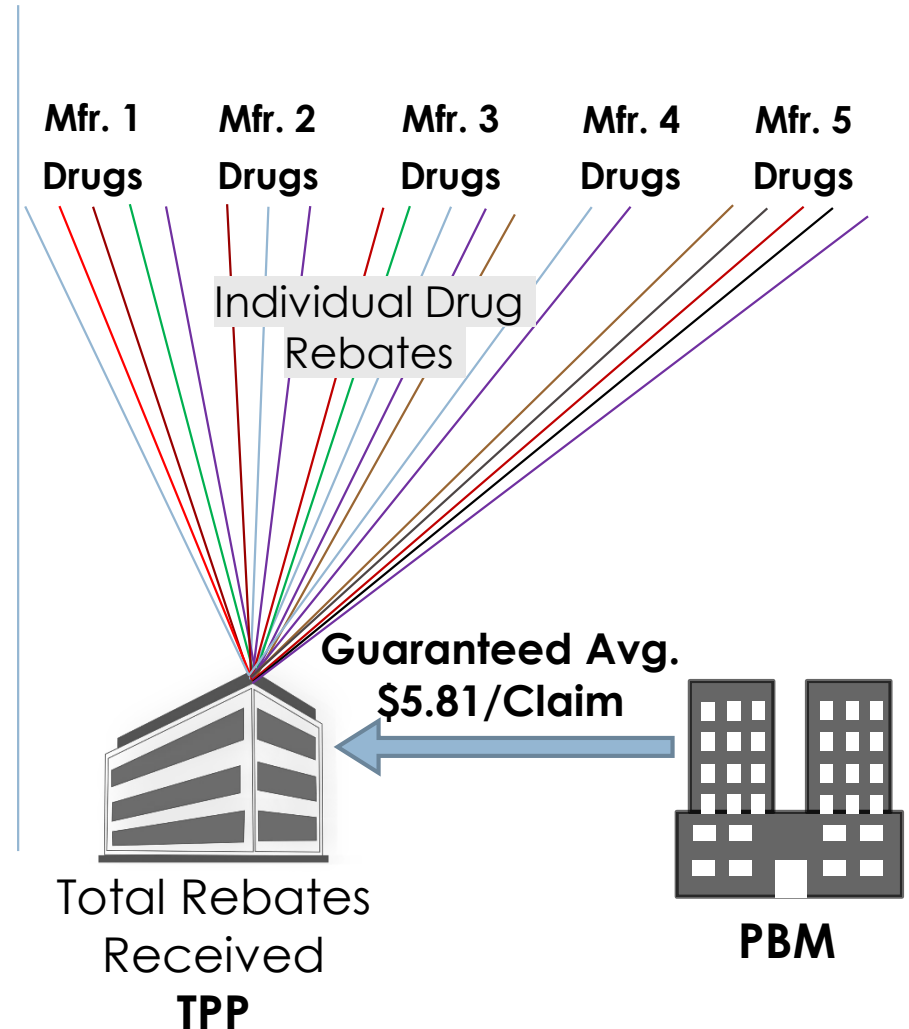
Mr. Dietz's only example:
one neighborhood
1994-96
(Dep. 223:17-224:25)

Rebate Guarantees Are Never Specific to a Particular Drug

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Rebate guarantees are:

- Based on **average** manufacturer rebates TPP **for all drugs**
- Never specific to a single drug (Dietz agrees: Dep. 236:2–237:3)
- Paid after the quarter or year, based on all claims reimbursed
- Involving different parties (TPP/PBM) than end purchase (TPP/Consumer)
- Rarely violated
- Unlikely to be material



PBMs Dispute The Significance of Rebate Guarantees

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James Calandriello, Express Scripts (*In Re: Restasis*), April 9, 2019

“historically, adjustments to Express Scripts’ original [rebate guarantee] estimates have been immaterial.” (¶14)

Kent Rogers, OptumRx (*In Re: Restasis*), April 4, 2019

OptumRx does not “book losses for individual drugs on guaranteed rebates” (¶12)

“While OptumRx may retain, in certain cases, compensation through spread pricing, rebates, or administrative fees, that compensation is payment for services that OptumRx provides and not payment for prescription drugs that are dispensed to health plan members and which are the financial responsibility of the health plan” (¶6)

Exclusions

2. Federal and State Governmental Entities

Federal and State Governmental Entities

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- ☐ Exclusion: “[A]ll federal and state governmental entities except for cities, towns, municipalities or counties with self-funded prescription drug plans”
- ☐ Government Plans use PBMs, just like Commercial Plans
- ☐ PBMs know their clients and can screen out federal and state government entities



Medicare Part D Plans are Commercial Plans run by private insurers; they are **not** government entities

Medicare Part D Plans Easily Identified From Centers for Medicare & Medicaid Services (CMS) Online Reports

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SilverScript

Contract Number	Plan ID	Organization Type	Plan Type	Offers Part D	Organization Name	Organization Marketing Name	Plan Name	Parent Organization	Contract Effective Date	Enrollment
S5601	002	PDP	Medicare Prescription Drug Plan	Yes	SILVERSCRIPT INSURANCE COMPANY	SilverScript	SilverScript Choice (PDP)	CVS Health Corporation	1/1/2006	23,453
S5601	003	PDP	Medicare Prescription Drug Plan	Yes	SILVERSCRIPT INSURANCE COMPANY	SilverScript	SilverScript Plus (PDP)	CVS Health Corporation	1/1/2006	678

EmblemHealth

Contract Number	Plan ID	Organization Type	Plan Type	Offers Part D	Organization Name	Organization Marketing Name	Plan Name	Parent Organization	Contract Effective Date	Enrollment
H3330	021	Local CCP	HMO	Yes	HEALTH INSURANCE PLAN OF GREATER NEW YORK	EmblemHealth Medicare HMO	EmblemHealth VIP (HMO)	EmblemHealth, Inc.	7/1/1987	12,470
H3330	029	Local CCP	HMO	Yes	HEALTH INSURANCE PLAN OF GREATER NEW YORK	EmblemHealth Medicare HMO	EmblemHealth Dual Eligible (HMO SNP)	EmblemHealth, Inc.	7/1/1987	9,659

Humana

Contract Number	Plan ID	Organization Type	Plan Type	Offers Part D	Organization Name	Organization Marketing Name	Plan Name	Parent Organization	Contract Effective Date	Enrollment
H1036	025	Local CCP	HMO	Yes	HUMANA MEDICAL PLAN, INC.	Humana Medical Plan, Inc.	Humana Gold Plus H1036-025 (HMO)	Humana Inc.	2/1/1986	14,142
H1036	040	Local CCP	HMO	Yes	HUMANA MEDICAL PLAN, INC.	Humana Medical Plan, Inc.	Humana Gold Plus H1036-040 (HMO)	Humana Inc.	2/1/1986	12,903

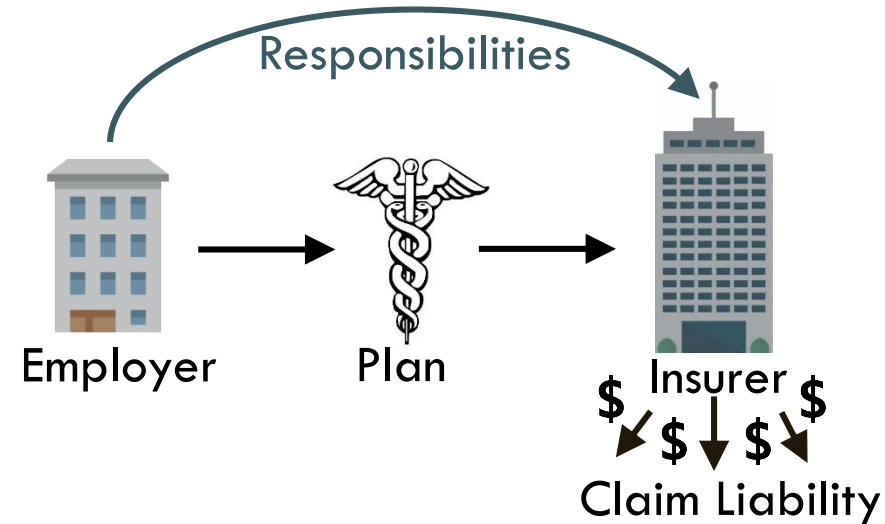
Exclusions

3. Fully-Insured Plans

What is a “Fully-Insured Plan”?

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- Sponsor not responsible for claims: arranges a commercial insurer to provide benefits in exchange for premium
- BIN and PCN numbers used to route claims identify actual payor; Group ID identifies employer sponsor



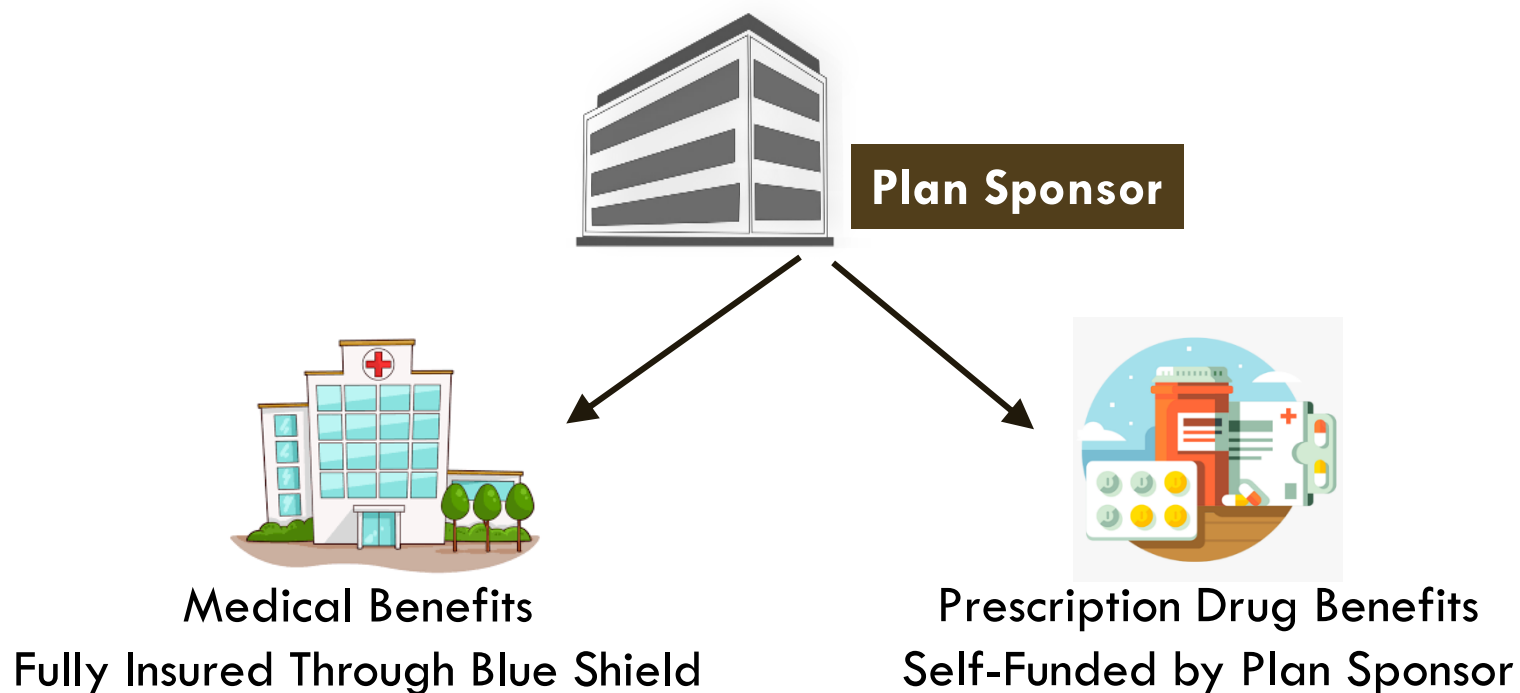
*“For employers or other entities that are **fully insured (not at risk)**, the card issuer ID field **must contain** the HPID [Health Plan ID] or OEID [Other Entity ID] of **the insurance entity**”*

(NCPDP, NCPDP Health Care Identification Card Fact Sheet, 2017)

What is a “Mixed Insured” Plan?

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- “Mixed-Insured”: a term in IRS Form 5500 (data not needed)
- Typically, a Plan offering multiple benefits, with one self-funded and the other fully insured

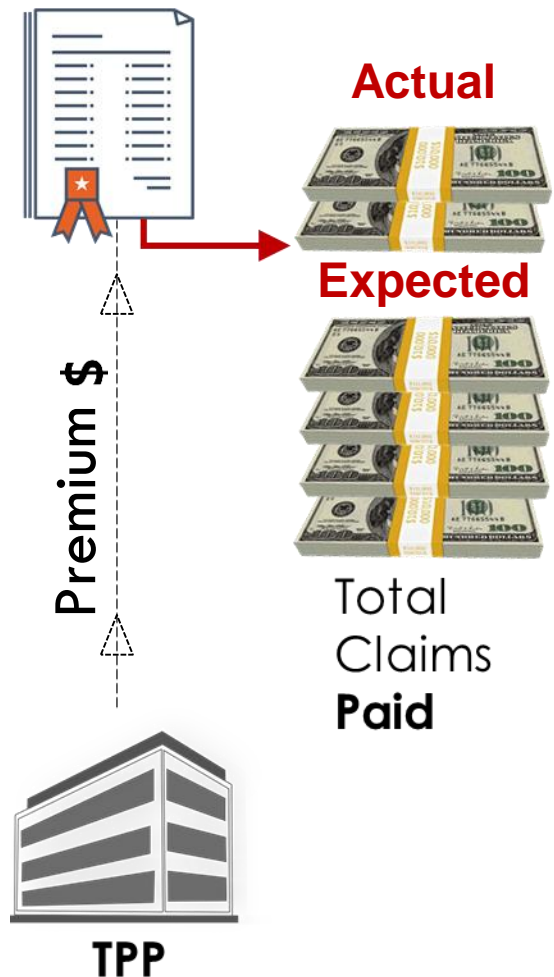


Only the method of funding the prescription drug benefits matters

Stop Loss Insurance Does Not Contribute to The End Purchase

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Stop-Loss Policies Are A Separate Contract That Some TPPs Purchase

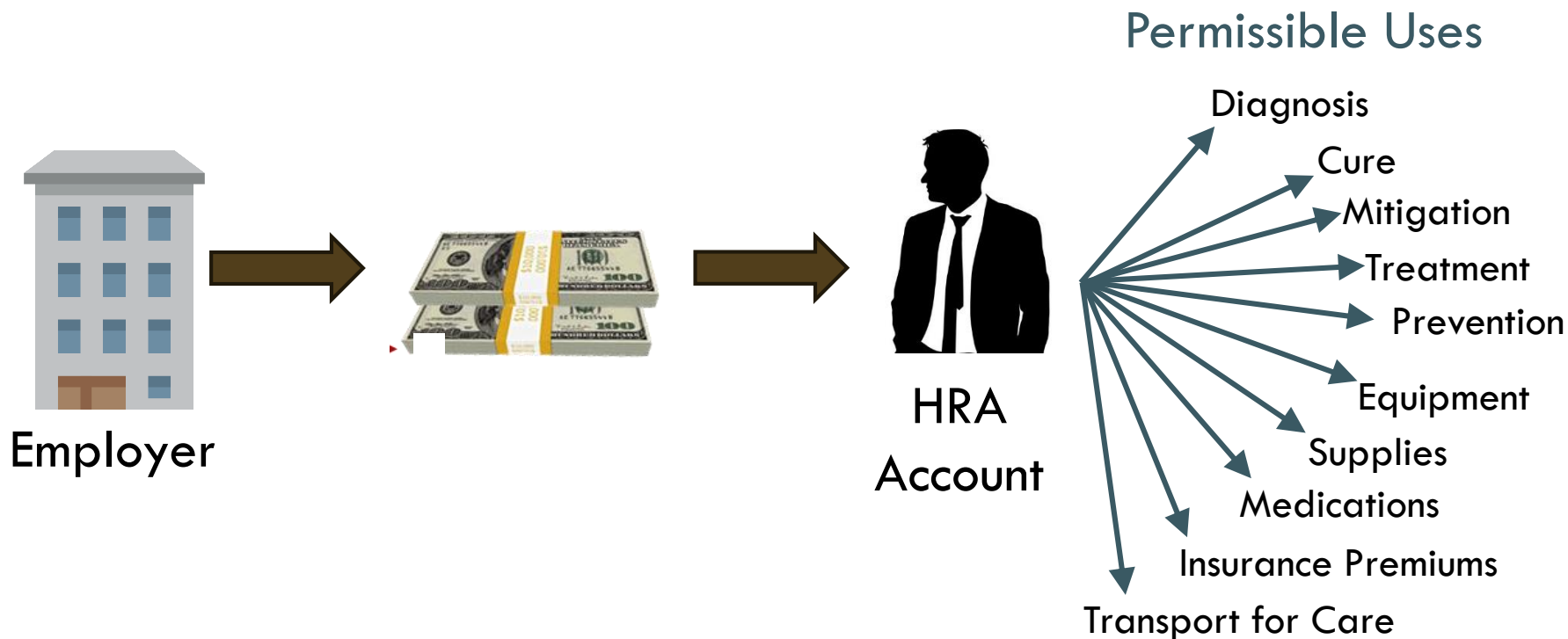


- **Different Contract:** Financial and risk management tool
- **Different Parties:** Stop Loss insurer never responsible to pay member claims
- **Different Time:** Annual or quarterly look-back
- **Different Expense:** Only triggered if total payments of *all medical or drug* claim far exceed expected levels

HRA Money Belongs to Employees, Not Employers—It is Irrelevant to TPP Losses

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Health Reimbursement Arrangement (HRA) allows employer to give employee funds (tax-exempt) to use for healthcare-related expenses. Employee chooses how to spend.



Proposed Amendments to Class Definition

Proposed Amendments Do Not Affect Ascertainability

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Original Definition

Brand **or** Generic Purchases
7/1/2012-11/18/2019

Proposed Amendments

Brand Subclass

Brand Purchases Only
11/15/2014-12/11/2016

Generic Subclass

Generic Purchases Only
12/12/2016-11/18/2019

Exclusions

Specific Medicare
Part D Plans

TPP Clients of
OptumRx
(PBM)

Class Period is shorter; all original Exclusions remain;
Excluded Part D Plans are listed by CMS; OptumRx can identify its Clients